

REMARKS

The Office Action has been carefully considered. Claims 30-35 are pending.

Reconsideration and allowance of the present application in view of the following remarks are respectfully requested.

I. CLAIM REJECTION UNDER § 102(e)

Claims 30-31 have been rejected under 35 U.S.C. §102(e) as allegedly being anticipated by United States Patent No. 6,171,327 to Daniel ("Daniel"). This rejection is respectfully traversed.

Independent claim 30 recites a medical device having at least a coated tube-like portion which is insertable or implantable into the body of a patient, wherein the portion has a first surface and a second surface which are adapted for exposure to body tissue of the patient, wherein at least a part of the first surface is covered with a coating comprising a first biologically active material to be released from the coating, the second surface is substantially free of the first biologically active material, the coated portion comprises at least one laser-ablated opening extending through the coated portion, and the medical device is manufactured by: (a) obtaining a structure having the first surface and the second surface; (b) coating at least a portion of the first surface with a first coating material; and (c) ablating the coated structure with a laser to form at least one opening extending through the coated portion. Claim 31 depends from claim 30 and, thus, also includes the recitations of claim 30.

A claim is anticipated only if *each and every* element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added).

Daniel discloses a filter 21 which "includes a membrane 22" that "defines a plurality of apertures 23 extending therethrough" and that "[a]pertures 23 can be drilled . . . using excimer laser or other ablation techniques." Column 4, lines 14-16 and 58-59. Daniel further discloses that filter 21 (which includes the membrane and apertures) "can be coated with various coatings to impart functional performance characteristics, one example being a thrombus resistant coating such as Heparin to discourage clot formation on [the] filter." Column 4, lines 50-58.

Daniel does not teach or suggest a medical device having a first surface that is covered with a coating having a first biologically active material to be released from the

coating and a second surface that is substantially free of the first biologically active material. Daniel also does not teach or suggest at least one laser-ablated opening extending through a coated portion, wherein the opening is formed by coating at least a portion of the first surface with a first coating material; and ablating the coated structure with a laser to form at least one opening extending through the coated portion.

According to MPEP § 2113, “[t]he structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where . . . the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product.” As stated in the present specification, the “polymer coating, when applied by methods in the art, tends to create bridges at small gaps or corners between stent struts. Also, in the conventional methods, wherein a coating process takes place after a shaping process, it is almost impossible to selectively coat the stent. For example, it is impossible to coat one side of a stent without coating the other side or to apply different coatings to the outside and inside of a stent.” Present specification, page 1, line 32, to page 2, line 1. In contrast, “medical devices having multiple coating layers and a complicated geometry pattern can also be easily manufactured by the method of the present invention without flaws such as polymer-bridges at gaps or corners.” Specification, page 9, lines 21-23. Thus, the resultant medical device of Daniel would not be the same as that presently claimed.

Thus, it is believed that claim 30 and claim 31 depending therefrom are patentable over Daniel. Accordingly, withdrawal of this rejection and allowance of claims 30-31 are respectfully requested.

II. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)

A. Claims 30-35 are Patentable Over U.S. Patent No. 6,096,070 to Ragheb *et al.* (Ragheb) in View of Daniel.

Claims 30-35 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,096,070 to Ragheb *et al.* (Ragheb) in view of Daniel. This rejection is respectfully traversed.

Independent claim 30 recites a medical device having a coated portion that has at least one laser-ablated opening extending through the coated portion. Claims 31-35 depend from claim 30 and, thus, also include the recitations of claim 30.

As acknowledged by the Examiner, Ragheb does not teach or suggest a medical device having a coated portion that has at least one laser-ablated opening extending through the coated portion, as required by the present claims.

To remedy the deficiencies of Ragheb, the Examiner relies on Daniel. However, Daniel cannot be applied as a basis for an obviousness rejection. Pursuant to 35 U.S.C. § 103(c)(1) and M.P.E.P. § 706.02(k), a reference which qualifies as prior art only under one or more of subsections 35 U.S.C. § 102(e), (f), and (g) does not qualify as a prior art reference against an application if: (1) such application was pending on or after December 10, 2004; and (2) the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Daniel did not issue until after the present application was filed, and thus can only qualify as prior art under 35 U.S.C. § 102(e). The present application was pending on December 10, 2004. In addition, at the time the present invention was made, the inventors of Daniel and the inventor of the present application were subject to an obligation to assign their respective inventions to Scimed Life Systems, Inc. Pursuant to this obligation, an Assignment from the inventors of the invention in Daniel to Scimed Life Systems, Inc. was recorded in the U.S. Patent and Trademark Office (“USPTO”) on May 24, 1999, at Reel 009978, Frame 0289, and an Assignment from the inventor of the present invention to Scimed Life Systems, Inc. was recorded in the USPTO on November 28, 2000, at Reel 011377, Frame 0059.

Thus, Daniel does not qualify as prior art that can be used in 35 U.S.C. § 103(a) rejection. Accordingly, withdrawal of this rejection and allowance of claims 30-35 are respectfully requested.

B. Claims 30-35 are Patentable Over Ragheb in View of U.S. Patent No. 6, 471,721 to Dang *et al.* (Dang).

Claims 30-35 have also been rejected under 35 U.S.C. §103 as allegedly being unpatentable over Ragheb in view of Dang. This rejection is respectfully traversed.

As discussed above, Ragheb does not teach or suggest a medical device having a coated portion that has at least one laser-ablated opening extending through the coated portion, wherein the opening is formed by ablating the coated structure with a laser to form at least one opening extending through the coated portion. Ragheb does not even disclose or suggest forming openings after its device has been coated.

Dang does not remedy the deficiencies of Ragheb. Dang does not disclose or suggest “a coating comprising a first biologically active material to be released from the coating” as required by the present claims. Dang does not even disclose or suggest the use of a first biologically active material to be released from the coating. Since Dang does not disclose or suggest a coating comprising a first biologically active material, Dang also does not disclose or suggest at least one laser-ablated opening extending through such coated portion.

The Examiner states that Dang “discloses stent 10 being made by laser cutting through stent body material including coating 14.” Office Action, pages 3-4. However, Dang does not disclose or suggest that its coating 14 comprises a biologically active material to be released from the coating as required by the present claims. Instead, Dang’s coating 14 is a stainless steel coating which is “applied by sputtering, a method of depositing a metallic film through the use of electric discharge.” Column 5, line 67 to column 6, line 3.

Thus, like Ragheb, Dang also does not teach or suggest a medical device having a coated portion that comprises a biologically active material to be released from the coating and that has at least one laser-ablated opening extending through the coated portion, wherein the opening is formed by ablating the coated structure with a laser to form at least one opening extending through the coated portion. Thus, it is believed that the present claims are patentable over Ragheb in view of Dang.

Moreover, one skilled in the art would not find motivation in the disclosures of Ragheb and Dang to combine these references where Ragheb is directed to a medical device “incorporating drugs or bioactive agents” for controlled release in the body (Ragheb, column 1, lines 12-13; and column 3, lines 9-11), and Dang is directed to a stent that includes radiopaque material to enhance visibility of the stent under fluoroscopy (Dang, column 1, lines 9-12) and does not disclose or suggest including a drug or bioactive agent to be released from the stent.

Thus, it is believed that claims 30-35 are patentable over Ragheb and Dang. Accordingly, withdrawal of this rejection and allowance of claims 30-35 are respectfully requested.

III. CONCLUSION

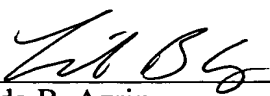
As the claim rejection and claim objection have been overcome, all pending claims are believed to be in condition for allowance. Should the Examiner not agree with Applicant's position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the allowance of the application.

Respectfully submitted,

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Enclosures